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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

HUNNICUTT, RACHEL KAPUST

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1647

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/063,567

Applicant(s)

EATON ET AL.

Examiner

Rachel K. Hunnicutt

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

Applicant's amendment filed August 9, 2004 is acknowledged. Claims 1-13 have been canceled. Claims 14-16 are new. Claims 14-16 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The rejection of claims 1-6 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 1-5 and 12-13 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 1-5 and 12-13 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 1-12 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,546 is withdrawn in response to Applicant's cancellation of these claims. The rejection of claims 1-13 under 35 U.S.C. 102(e) as being anticipated by Chen, Ople *et al.*, and Fox *et al.* is withdrawn in response to Applicant's cancellation of these claims.

The declaration filed on August 9, 2004 under 37 CFR 1.131 has been considered, however a declaration filed under 37 CFR 1.131 must be signed by all of the inventors of the subject matter of the rejected claims. The declaration filed on August 9, 2004 was only signed

Art Unit: 1647

by William Wood. Thus, the declaration cannot be considered as evidence. However, the international patent application publication WO 99/63088 filed on June 2, 1999 (filed as Exhibit 1) is duly noted. The sequences of the current application were disclosed in U.S. provisional application 60/089653 filed on June 17, 1998. Therefore, the current application has a priority date of June 17, 1998. The priority date of June 17, 1998 is prior to the effective filing dates of U.S. Patent No. 6,468,546, Chen, Ople *et al.*, and Fox *et al.* As such, new claims 14-16 are not anticipated by U.S. Patent No. 6,468,546, Chen, Ople *et al.*, and Fox *et al.*

Applicants state in their response that the provisional applications cited in the different publications were not available to Applicants. Applicants are referred to the public PAIR website (<http://portal.uspto.gov/external/portal/pair>), which has made IFW scanned documents available to the public since July 30, 2004. All of the cited provisional applications can be viewed on the PAIR website.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 31 and 35). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

The rejection of claims 1-13 under 35 U.S.C. 101 is withdrawn in response to Applicant's cancellation of these claims. New claims 14-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection is applied to new claims 14-16 for reasons of record on p. 3-4 of the office action of paper no. 0604.

Applicants argue that there are at least two specific and substantial utilities for the claimed polypeptides: (1) the polypeptides are useful as diagnostic targets for the determination of esophageal or lung tumor in human tissue samples of previously unknown morphology; and (2) the polypeptides are useful as immunogens for the preparation of antibodies that bind to the

Art Unit: 1647

polypeptide comprising SEQ ID NO: 60. Applicants refer to the data in Example 18 which demonstrates that the claimed protein is “detectably overexpressed in human esophageal tumor as compared to its normal tissue counterpart...and is also detectably overexpressed in human lung tumor as compared to its normal tissue counterpart” (p. 6 of response).

Applicant's arguments have been fully considered but have not been found to be persuasive. Tissue-specific expression such as that found in Example 18 is not specific to the polynucleotide. It does not depend on any characteristics of the nucleic acid molecule itself. Regarding Applicant's argument that the claimed polypeptide has a specific and substantial utility as being used as a diagnostic target for the determination of esophageal or lung tumor, utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. In Example 18, the specification merely states that the gene is “more highly expressed” in one tissue as compared to another. There is no guidance in the specification as to how high the levels are. There is no information in the specification as to the types of tumors, malignant or benign, that are affected. Applicants do not provide any evidence that indicates what the differences were or whether the results were statistically significant. Applicants have provided no indication of the nature of number of samples that were used. The art teaches that individual changes may be associated with clonal expansion, which would not be characteristic of the class of tumors as a whole (see, for example, Bover *et al.* 1998, *Cell. Mol. Biol.* 44(3): 493-504). The only thing Applicants teach is that the gene was “more highly expressed”, and this does not enable the skilled artisan to differentiate amongst expression levels in order to diagnose any diseases.

Because the claimed polypeptides do not have a utility as a diagnostic marker for esophageal or lung tumors, they also have no utility as immunogens for the preparation of antibodies. Any polypeptide can be used to make antibodies, so that ability is not specific to the claimed polypeptide. There would only be a specific utility if the antibodies had a utility, and, as previously stated, since the claimed polypeptides are not useful as diagnostic markers, antibodies against them would also not be useful as diagnostic probes. The antibodies would not be diagnostically useful because the skilled artisan would not know how to use them to diagnose anything.

Claim Rejections - 35 USC § 112

The rejection of claims 1-13 under 35 U.S.C. 112, first paragraph, for lack of enablement due to the invention not being supported by a specific or substantial asserted utility or a well-established utility, is withdrawn in response to the cancellation of these claims. New claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, because since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Conclusion

NO CLAIMS ARE ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
10/13/04


JANET ANDRES
PRIMARY EXAMINER